



Serial No. 09/966,783

REMARKS/ARGUMENTS

In response to the Office Action mailed January 24, 2006, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, Claims 1 and 20 are amended, no claims have been added, and no claims have been cancelled so that Claims 1-40 are currently pending. No new matter has been introduced.

Claims 1-10, 20, 21 and 28-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,472,702 to Muth et al (Muth) in view of U.S. Patent No. 5,749,203 to McGowan, Jr. (McGowan) and further in view of EP 0 568 310 to Mitchell (Mitchell). Claims 22-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muth in view of McGowan and Mitchell and further in view of U.S. Patent No. 5, 464,580 to Popescu et al. (Popescu). Claims 11-13 and 32-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Muth in view of McGowan and Mitchell and further in view of U.S. Patent No. 6, 025, 414 to Rich (Rich) and U.S. Patent No. 3, 675, 647 to Pharriss et al. (Pharriss). Claims 14-19 and 35-40 were rejected under 35 U.S. C. § 103(a) as being unpatentable over Muth in view of McGowan and Mitchell and further in view of WO 00/38754 to Gingras (Gingras). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947

F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).”

Both Muth and McGowan are directed to methods of sterilization. In Muth a device and a protein are being sterilized whereas in McGowan a device is sterilized. However, neither of the references, whether taken alone or in combination, discloses or even remotely suggests sterilizing a medical device coated with a compound that inhibits mTOR and binds FKBP12 as is claimed in the present invention. This is a specific set of compounds and not set forth in these two references. However, the Examiner has now cited Mitchell which disclosed a composition comprising heparin and rapamycin. It is respectfully submitted that the Examiner is utilizing hindsight along with the claims as a template to pick and choose the references and this is not permitted.

Applicants respectfully submit that the Examiner is using impermissible hindsight in combining the references. As stated above, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In *re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Furthermore, recently the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") restated the legal test applicable to rejections under 35

U.S.C. 103(a) (In re Rouffet, 47 USPQ2d 1453 (Fed. Cir., July 15, 1998)). The Court stated: [V]irtually all [inventions] are combinations of old elements. Therefore an Examiner may often find every element of a claimed invention in the prior art. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an Examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." To prevent the use of hind sight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness. The Board [of Appeals] did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the field of the art. If such a rote indication could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct the suggestion to combine requirements stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness. In re Rouffet, 47 USPQ2d 1457-58 (Fed. Cir., July 15, 1998) (citations omitted, emphasis added). More recently, the Federal Circuit again dealt with what is required to show a motivation to combine references under 35 U.S.C. 103(a). In this case the court reversed the decision of the Board of appeals stating:

[R]ather than pointing to specific information in Holiday or Shapiro that suggest the combination..., the Board instead described in detail the similarities between the Holiday and Shapiro references and the claimed invention, noting that one reference or the other-in combination with each other... described all of the limitations of the pending claims. Nowhere does the Board particularly identify any suggestion, teaching, or motivation to combine the ... references, nor does the Board make specific-or even inferential-findings concerning the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any factual findings

that might serve to support a proper obviousness analysis. In re Dembiczak, 50 USPQ2d 1614, 1618 (Fed. Cir., April 28, 1999) (citations omitted, emphasis added).

Thus, from both In re Rouffet and In re Dembiczak it is clear that the Federal Circuit requires a specific identification of a suggestion, motivation, or teaching why one of ordinary skill in the art would have been motivated to select the references and combine them or an identification of the level of skill in the art at the time of the invention which would make him likely to combine his skill with the teachings of the art to come up with the invention. This the Examiner has not done. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

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The Reply raises no new issues and places the application in form for allowance therefore; entry is proper and earnestly solicited.

Respectfully submitted,

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